

### **REMARKS**

Claims 1-30 are pending in the application. Claims 31-42 have been canceled as drawn to non-elected inventions. Claims 1, 2, 5-11, 14-18, 20-26, 29, and 30 have been amended. Support for these amendments can be found throughout the specification as-filed, *e.g.* at page 2, lines 24-28; page 4, lines 15-20; page 5, lines 16-22; page 8, lines 12-13; and page 13, lines 11-25 of the specification. No new matter has been added.

### **Specification**

The Examiner has objected to the disclosure on page 18 (*See* Office Action at page 2). The specification has been amended to correct the various informalities identified by the examiner.

### **Rejections under 35 USC § 112, first paragraph**

Claims 1-10, 12-24, and 26-30 are rejected for lack of enablement (*See* Office Action at pages 2-3). The rejection is traversed as it applies to the claims as amended.

The claims have been amended to specify that the subject has symptoms of Crohn's disease or inflammatory bowel disease. For example, Example 1 illustrates that increased levels of specific anti-glycan antibodies are detected in the serum of patients with Crohn's disease. Applicants request withdrawal of the rejection for lack of enablement.

**Rejections under 35 USC § 112, second paragraph**

Claims 1-30 are rejected as indefinite, on various grounds (*See* Office Action at pages 3-4). The claims have been amended to address the rejections.

**Rejections under 35 USC § 101**

Claims 22-30 are provisionally rejected for statutory double-patenting in view of claims 22-30 of USSN 10/843,033 (*See* Office Action at page 5). Applicants will address this rejection upon the indication of allowable subject matter in either application.

**Rejections under 35 USC § 102(b)**

Claims 1-8, 11-15, 17-19, and 21-28 are rejected as anticipated by Main *et al.* BMJ 297:1105, 1988 ("Main") in light of Applicants' disclosure and/or Sendid *et al.*, Clin. Diagn. Lab. Immunol. 3:219, 1996 ("Sendid"), and/or Wakshull *et al.*, US Patent No. 6,294,321 ("Wakshull"). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 1 and claim 21, from which depend the remaining claims subject to the rejection, have been amended to require identifying at least one specific anti-glycan antibody that is recited in the claims. Main does not expressly or inherently describe a method with these features.

According to the Examiner, Main describes detection of IgG and IgA antibodies to a crude extract of *Saccharomyces cerevisiae* (ASCA) in Crohn's disease (CD), but not ulcerative colitis (UC), patient samples (*See* Office Action at page 6). However, there is no teaching or suggestion in Main of a method that requires specifically identifying the particular anti-glycan antibodies recited in the claims.

Claims 1-8, 11-20, and 22-28 are rejected as anticipated by Sendid in light of Applicants' disclosure and/or Wakshull. According to the Examiner, Sendid detected antibodies to *Saccharomyces cerevisiae* (ASCA) cells in the circulation of Crohn's disease (CD), but not ulcerative colitis (UC), patient samples by immunofluorescence (*See Office Action at page 6*). The Examiner states that Sendid inherently detected antibodies to the glycan epitopes. However, there is no teaching or suggestion in Sendid of a method that requires specifically identifying the particular anti-glycan antibodies recited in the claims.

Claims 22, 24 and 26-30 are rejected as anticipated by Quinton *et al.*, Gut 42:788, 1998 ("Quinton") in light of Walsh *et al.*, US Patent No. 6,218,129 ("Walsh"). According to the Examiner, Quinton discriminated ulcerative colitis (UC) from Crohn's disease (CD) by determinations of anti-neutrophil cytoplasmic auto-antibodies in the serum of patients and controls (*See Office Action at page 6*). The Examiner states that Quinton detected at least IgG and IgA ASCA. However, there is no teaching or suggestion in Quinton of a method that requires specifically identifying the particular anti-glycan antibodies recited in the claims.

Applicants additionally note that not all *Saccharomyces cerevisiae* strains elicit antibodies diagnostic of CD or UC. Sendid tested antibodies in serum of CD and UC against various strains of *Saccharomyces cerevisiae* (Su1, Sd, BM156, BM151, and CBS1315). Only antibodies to specific strains (Su1 and Sd) were specific for Crohn's disease. However, antibodies to whole cells of strain BM156, BM151, and CBS1315 were not specific for CD. (see table 1, page 221 of Sendid). In contrast, the invention now claimed associates antibodies to specific glycans with the presence of a particular inflammatory bowel disease.

Applicants request reconsideration and withdrawal of the rejection for anticipation.

**Rejections for Obviousness-type Double Patenting**

Claims 1-21 are provisionally rejected for obviousness-type double-patenting in view of claims 1-21 and 31-42 of USSN 10/843,033 (*See Office Action at page 7*). Applicants will address this rejection upon the indication of allowable subject matter in either application.

Claims 1-30 are provisionally rejected for obviousness-type double-patenting in view of claims 1-3, 7-12, and 18-29 of USSN 11/351,185 (*See Office Action at page 8*). Applicants will address this rejection upon the indication of allowable subject matter in either application.

Claims 1-30 are provisionally rejected for obviousness-type double-patenting in view of claims 1-3, 7-12, and 18-29 of USSN 11/364,964 (*See Office Action at page 8*). Applicants will address this rejection upon the indication of allowable subject matter in either application.

On the basis of the foregoing amendments and remarks, Applicants submit the pending claims are in condition for allowance. Such action is respectfully requested. The Commissioner is authorized to charge any fees that may be due to Deposit Account No. 50-0311, Reference No. 25681-502 P.

Respectfully submitted,



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